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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,528	03/23/2001	Roger D. Kamm	0492611-0375 (MIT-8802)	5331

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EXAMINER
YU, JUSTINE ROMANG

ART UNIT	PAPER NUMBER
3764	

DATE MAILED: 10/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

LC

Office Action Summary	Application No.	Applicant(s)	
	09/815,528	KAMM ET AL.	
	Examiner	Art Unit	
	Justine R Yu	3764	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-54 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-54 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

2. The disclosure is objected to because of the following informalities: on pages 3 and 5, the symbol ". 1" is not understood.

Appropriate correction is required.

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Drawings

4. The drawings are objected to because lead lines for reference numbers and descriptions in figures 1A and 1B are missing. In addition, figures 4 and 5 each includes three different tables and should be designated by different figure numbers. A proposed drawing correction or

corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the compression apparatus in the independent claims, the inflatable bladder, bladder containing liquid, a series of cuffs containing at least one inflatable bladder, stretchable band, blood oxygen detector, pulse oximeter, EKG detector, blood pressure detector, heating or cooling means, means for accelerating the withdrawal of fluid, vacuum pump, negative pressure reservoir, mounting means, Velcro, buttons, snaps, elastic band, zippers, gas compressor, tank of pressurized gas, balloon, computer, and tension controlling means must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Some examples if such errors are:

In claim 1, "providing a patient" is improper because it appears that the applicant attempts to claim a human being.

In claim 3, the term "shear stress seen by the vascular endothelial cells of the patient" is indefinite because it is not clear how to see the shear stress and what is the structural element being used to see such stress. Furthermore, it appears that the applicant attempts to claim human anatomy.

In claim 8, the term "is sufficient to cause a temporary collapse" is vague and indefinite since the condition varied with different patients.

In claim 13, it is not clear what is meant by "is timed with the cardiac cycle of the patient", and how and by what structural element being used to perform the recited function.

In claim 15, line 15, "NO" is not understood.

In claim 19, "apparatus is attached to at least one extremity of the patient" is indefinite because it appears that the applicant attempts to claim human anatomy.

In claim 23, "may" is vague and indefinite.

In claims 27-30, the recitation of claiming the patient is indefinite.

In claim 35, line 18 "graded sequential compression" is unclear as which disclosed part is being used to perform the recited function.

In claim 40, "liquid" lacks antecedent basis.

In claim 41, "the withdrawal of fluid" lacks antecedent basis. In addition, it is not clear what structure is being suggested by "negative pressure reservoir".

In claim 45, "Velcro" is a trademark.

In claim 54, it is not clear which disclosed part that the tension control means is being referred.

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 3-7, 12, and 14-18 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. Applicant in his claims recites that his method is able to obtain certain results within the body of the patient: i.e., the reverse in direction of shear stress seen by the vascular endothelial cells of the patient; causes 50% - 400% change in the shear stress seen by the vascular endothelial cells of the patient; induces secretion of various factors which including angiogeneises, platelet-derived growth factor, fibroblast-derived growth factor, etc.. Since there has no scientific data and evidences to support the claimed treatment method steps would be able to obtain such claimed results, the claimed method lacks patentable utility.

10. Claims 3-7, 12, and 14-18 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

Note, because the claimed invention is not supported by a specific asserted utility for the reasons set for the above, credibility cannot be assessed.

Claims 3-7, 12, and 14-18 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1, 9, 10, 13, 19-23, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Neeman et al (5,014,681).

Neeman teaches a method for treating low blood flow comprising steps of attaching a compression apparatus 3 to a body part of the patient and applying graded sequential compression to the body part with a maximum pressure less than 200 mmHg (column 7, lines 13-15).

13. Claims 1, 9, 10, 12, 13, 19, 20, 23, 25, 26, are rejected under 35 U.S.C. 102(b) as being clearly anticipated by McEwen et al (5,843,007).

McEwen teaches a device comprising a plurality of cuffs (4, 6), figure 2.

14. Claims 31-34 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Spielberg (3,859,989).

15. Claims 35-37, 39, 40, 44, 47, 49, and 51- 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Zheng et al (5,997,540).

Zheng teaches a device having a plurality of balloons 25, peak pressure 60 mm Hg (column 14, lines 30-31), a computer 7. Zheng in column 5, lines 15-24 and column 14, lines 22-24 discloses a blood oxygen detector, pulse oximeter, blood pressure detector. Zheng further discloses a cooling means 21, and an mounting means within the cuff for mounting the cuff to the body (figure 4C).

16. Claim 33 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Khouri (5,701,917).

Claim Rejections - 35 USC § 103

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 2-8, 11, 12, 14-18, 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neeman et al.

Regarding claims 2 and 27-30, Neeman does not explicitly discloses that the patient having a wound or with different diseases. The feature of using the compression method to treat patients with such diseases is considered as an obvious design preference within the knowledge of one skilled art.

Regarding claims 3-8, 12, and 14-18, it would have been obvious to a skilled artisan that Neeman's device would be able to perform the recited function since Neeman's device has the same structure as claimed.

Regarding claim 11, the feature of choosing a maximum delivery pressure such as less than 150 mm Hg is considered as an obvious design choice since using less than 150 mm Hg is well known in the art.

19. Claims 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neeman et al in view of Dillon (5,514,079).

Neeman does not explicitly disclose the compression is timed with cardiac cycle of the patient. However, Dillon teaches a pulse monitor 13 having an EKG 14 and timer 16 (column 6, lines 9-19). Therefore, it would have been obvious to one of ordinary skill in the art at the time

the invention was made to provide Neeman's device with a pulse monitor as taught by Dillon in order to enhance the treatment effect.

20. Claims 1-12, 14-22, 24-30, 35, 41-46, 48, 50, and 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cariapa et al (5,437,610).

Cariapa teaches a hydraulic system including sequentially compressible bladders (figures 1, 2) being attached to a body part of the patient. Cariapa lacks a detail description that the compression delivers a maximum pressure of less than 300, 250, 200, or 150 mm Hg. However, the feature of choosing the maximum compression pressure of less than such particular values are considered as obvious design choices, as is necessary and inherent upon various applications.

Regarding claim 21, the feature of attaching the compression device to the arm instead of the leg is considered as an obvious design choice since it appears that Cariapa's device would perform equally well by applying the device in the arm.

Regarding claim 25, figure 2 of Cariapa shows a series of cuffs each including an inflatable bladder.

Regarding claim 26, figure 1 of Cariapa shows the flexible band 24.

Regarding claims 41-43, notes the withdrawal pump 28 and reservoir 30.

Regarding claims 44-46 and 54, Cariapa teaches a Velcro 94 (mounting means or control means)but lacks buttons, snaps, elastic bands, or zippers. However, the feature of choosing different mounting means such as buttons, snaps, elastic bands, or zippers is considered as an obvious design choice since such mounting means are well known in the art.

21. Claims 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cariapa et al (5,437,610) in view of Dilton.

Cariapa lacks an EKG. However, Dilton teaches an EKG. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide Cariapa's device with an EKG as taught by Dilton, so as to provide a better control during the treatment.

Conclusion

22. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Fox (5,584,798), Pekanmaki et al (4,989,589), Cooper (5,000,164), Lapidus (3,920,006), Apstein (3,811,431), Albery et al (6,010,470), Vinmont (3,908,642), Proctor et al (5,109,832) are cited to show different therapeutic devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Justine R Yu whose telephone number is (703)308-2675. The examiner can normally be reached on 8:30am - 6:00Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (703)308-2698. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

Justine R Yu
Primary Examiner
Art Unit 3764

JY
September 29, 2002